January 12, 1999

CENTER FOR VETERINARY BIOLOGICS NOTICE 99-04

Subject: Completion of Part I of the Outline of Production for Vaccines, Bacterins, Antigens, and Toxoids

To: Veterinary Biologics Licensees, Permittees, and Applicants
Center for Veterinary Biologics, Licensing and Policy Development
Center for Veterinary Biologics, Laboratory
Center for Veterinary Biologics, Inspection and Compliance

The purpose of this Notice is to clarify how firms should complete Part I of the Outline of Production in accordance with 9 CFR 114.9(d). Conflicting interpretations have resulted in a great deal of variability. This Notice identifies specific information to be included in each section of Part I of the outline for these products.

Section I. A. "Microorganisms used. Give the isolation and passage history."

For each microorganism used to produce the product, provide the following information:

- Identification of the microorganism, including strain or isolate;

- Isolation and known passage history, including the number of passages since isolation in each type of medium, cell culture, and/or animal;

- Date of notification from the Center for Veterinary Biologics (CVB) that the Master Seed is eligible for use in production;

- Name and license number of the firm at the time notification is received from CVB that the Master Seed is eligible for use in production;

- Identification of the Master Seed as it appears on the stored Master Seed container label and licensee's records.

Section I. B. "Source and date of accession of each microorganism."

For each microorganism used to produce the product, indicate the date the current licensee obtained the Master Seed and from whom. If the Master Seed was obtained through a merger(s) or sublicensing agreement(s) with a current or former USDA licensed firm, provide the name and license number of such firm(s), and the effective date(s) of the relevant company merger(s) or agreement(s).

Section I. C. “Strains.”

Give the strain or isolate designation for each microorganism used to produce the product. If the microorganism is a generally recognized strain, specify the strain. Otherwise, provide the isolate designation as it appears on containers used to store the Master Seed.

Section I. D. “Proportions of each strain.”

- If the product contains only one strain or isolate for each fraction, mark this section “NA”.

- If some or all of the fractions of the product contain more than one strain or isolate, but in all cases the strains or isolates can be distinguished in the potency test, mark this section “NA”.

- If the product contains a fraction or fractions that contain more than one strain and/or isolate that cannot all be distinguished in the potency test, indicate the proportion of each strain and/or isolate in the fraction. The proportions of the strains in that fraction (expressed in percent) should be based on antigenic mass (not on volume of harvest fluids or other criteria). For each fraction the sum of the proportions should add up to 100 percent. For other fractions in the product that meet the first two criteria, indicate “NA”.

Firms should bring their Outlines of Production into compliance with this Notice before or at the next annual review.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics